Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385184	10/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Renal Associates, Pc	357 Tower Road, Dakota Dunes, SD	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory supervisor, the laboratory failed to achieve successful participation for the albumin test method. Unsatisfactory results had been received in two of three PT events (American Proficiency Institute 2023 Chemistry Core 2nd Event and 2023 Chemistry Core 3rd Event) resulting in unsuccessful PT participation. Refer to D2087
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a)

	Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the CASPER proficiency testing (PT) reports 153D and 155D, the laboratory's American Proficiency Institute (API) PT reports and interview with the laboratory supervisor, the laboratory failed to achieve a satisfactory score of 80% or above for the albumin test method for two of three events (API 2023 Chemistry Core 2nd Event and 2023 Chemistry Core 3rd Event). Findings include: 1. Review of the 10 /27/2023 CASPER Unsuccessful PT Report 153D revealed the laboratory received unsatisfactory scores (less than 80%) for the albumin test method in each of the two events identified above. Review of the 10/27/2023 CASPER Individual Laboratory Profile PT report 155D and API PT 2023 Chemistry Core 2nd and 2023 Chemistry Core 3rd event evaluation reports revealed scores of 20% and 20% for the albumin test method for each event. Review of the individual API albumin test method scores for the two API PT events revealed: a. 2023 Chemistry Core 2nd Event albumin results: *CH-06 was 3.0, the acceptable range was 2.3-2.9 grams/deciliter (g/dL). *CH-07 was 4.7, the acceptable range was 3.6-4.5 g/dL. *CH-09 was 5.5, the acceptable range was 4.3-5.4 g/dL. *CH-10 was 4.2, the acceptable range was 3.2-4.1 g/dL. b. 2023 Chemistry Core 3rd Event albumin results: *CH-11 was 5.4, the acceptable range was 4.3-5.3 g/dL. *CH-13 was 4.9, the acceptable range was 3.7-4.7 g/dL. *CH-14 was 4.7, the acceptable range was 3.4-4.2 g/dL. *CH-15 was 3.9. the acceptable range was 2.9-3.7 g/dL. Interview on 10/27/23 with the laboratory supervisor revealed the laboratory had been aware of the failures. The initial failures had been investigated. It was determined that both failures were due to a shift after calibration of the reagent.